K040801

MAY - 6 2004

SECTION 5 – 510(k) SUMMARY

a. Submitted by

Arrow International, Inc.
9 Plymouth Street
Everett, MA 02149

Contact Person:

William Paquin
Quality Assurance / Regulatory Affairs Manager
Phone: (617) 389-6400 ext. 4345
Fax: (617) 387-2157
e-mail: bill.paquin@arrowintl.com

Date summary prepared: March 25, 2004

b. Device

Trade Name:	Intra-Aortic Balloon (IAB)
Common Name:	Intra-Aortic Balloon Catheter
Classification Name:	Balloon, Intra-Aortic

c. Names of Predicate Devices and 510(k) Numbers

The following table contains the predicate devices which Arrow claims substantial equivalence.

Table 1: Predicate Devices

510(k)	Intra-Aortic Balloon Description	Catalog Numbers
K970689	IAB 8Fr, 30/40cc and, 10 Fr, 50cc with Peel-Away Hemostasis Device	IAB-042XX-U
K963920	IAB 8Fr, 30cc Arrow NarrowFlex Universal	IAB-04830-U
K993966	IAB 8Fr, 40cc Arrow NarrowFlex Universal	IAB-04840-U
K000729	IAB 8Fr, 30/40cc Arrow Ultra Series	IAB-058XX-U/IAB-68XX-U
K021462	IAB 8Fr, 30/40cc Arrow Ultra Series with Light Wave Sensor	IAB-058XX-LWS

d. Device Description

IAB's are designed to provide cardiac assist therapy. The devices are dual lumen percutaneously inserted Intra-Aortic IAB catheters, with two independent non-communicating lumens. The outer lumen is comprised of an inflatable bladder connected to the catheter distal tip and to the IAB tip outer surface. The inner lumen is comprised of a luer adapter connected to the proximal end of the inner lumen and to the IAB tip inner surface. The IAB inner lumen is used for placement of the device with a guidewire and the outer lumen is used to shuttle helium gas to and from the inflatable bladder. IABs are timed to inflate within the aorta during the diastolic relaxation of the heart and deflate during the systolic contraction of the heart, resulting in increased blood supply to the heart muscle and decreased work load for the left ventricle.

e. Intended use of the device

The IAB is utilized for intra-aortic balloon counterpulsation therapy, whereby balloon inflation in the aorta during diastole and deflation during systole increase blood supply to the heart muscle and decrease work of the left ventricle.

f. Technological characteristics

The results of the laboratory tests demonstrate that the device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2004

Arrow International, Inc.
c/o Mr. William Paquin
Quality Assurance/Regulatory Affairs Manager
9 Plymouth Street
Everett, MA 02149

Re: K040801
Arrow Intra-Aortic Balloon (IAB) Catheter
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon and Control System
Regulatory Class: Class III (three)
Product Code: DSP
Dated: March 25, 2004
Received: April 6, 2004

Dear Mr. Paquin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040801

Device Name: Arrow Intra-Aortic Balloon

Indications For Use:

-Refractory left ventricular failure
-Cardiogenic or septic shock
-Unstable refractory angina
-Impending infarction
-Ischemia-related ventricular arrhythmias
-Weaning from cardiopulmonary bypass
-Support and stabilization during coronary angioplasty
-Intraoperative pulsatile flow generation
-Associated mechanical complications of acute myocardial infarction
-Support and stabilization of high-risk patients undergoing diagnostic and non-surgical procedures
-Mitral Valvuloplasty
-Bridge to Ventricular Assist Device
-Prophylactic support for cardiac surgery
-Post-surgical myocardial dysfunction
-Cardiac Contusion

Prescription Use __X_____ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040801